Can we Trust Computational Modeling for Medical Applications?

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Operations in extreme environments such as spaceflight pose human health risks that are currently not well understood and potentially unanticipated. In addition, there are limited clinical and research data to inform development and implementation of therapeutics for these unique health risks. In this light, NASA's Human Research Program (HRP) is leveraging biomedical computational models and simulations (M&S) to help inform, predict, assess and mitigate spaceflight health and performance risks, and enhance countermeasure development. To ensure that these M&S can be applied with confidence to the space environment, it is imperative to incorporate a rigorous verification, validation and credibility assessment (VV&C) processes to ensure that the computational tools are sufficiently reliable to answer questions within their intended use domain. In this presentation, we will discuss how NASA's Integrated Medical Model (IMM) and Digital Astronaut Project (DAP) have successfully adapted NASA's Standard for Models and Simulations, NASA-STD-7009 (7009) to achieve this goal. These VV&C methods are also being leveraged by organization such as the Food and Drug Administration (FDA), National Institute of Health (NIH) and the American Society of Mechanical Engineers (ASME) to establish new M&S VV&C standards and guidelines for healthcare applications. Similarly, we hope to provide some insight to the greater aerospace medicine community on how to develop and implement M&S with sufficient confidence to augment medical research and operations.